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11 Attorneys for Defendant/Counterclaimant  
Handa Pharmaceuticals, LLC  
12

13 **IN THE UNITED STATES DISTRICT COURT**  
14 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
**SAN FRANCISCO DIVISION**

|    |                                  |   |                                  |
|----|----------------------------------|---|----------------------------------|
| 15 | TAKEDA PHARMACEUTICAL CO., LTD., | ) | Case No. 3:11-cv-0840-CRB        |
| 16 | TAKEDA PHARMACEUTICALS NORTH     | ) |                                  |
|    | AMERICA, INC., TAKEDA            | ) |                                  |
| 17 | PHARMACEUTICALS LLC, AND TAKEDA  | ) |                                  |
|    | PHARMACEUTICALS AMERICA, INC.,   | ) | Hon. Charles R. Breyer, U.S.D.J. |
| 18 |                                  | ) |                                  |
|    | Plaintiffs/Counterdefendants,    | ) |                                  |
| 19 |                                  | ) |                                  |
|    | v.                               | ) |                                  |
| 20 |                                  | ) |                                  |
|    | HANDA PHARMACEUTICALS, LLC,      | ) |                                  |
| 21 |                                  | ) |                                  |
|    | Defendant/Counterclaimant.       | ) |                                  |
| 22 |                                  | ) |                                  |
| 23 |                                  | ) |                                  |

24 **DEFENDANT HANDA PHARMACEUTICALS, LLC'S ANSWER**  
25 **TO PLAINTIFF'S CORRECTED FIRST AMENDED COMPLAINT**  
26 **AND COUNTERCLAIMS**  
27  
28

1 Defendant Handa Pharmaceuticals, LLC (“Handa”) hereby answers the Corrected First  
2 Amended Complaint of Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals  
3 North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc.  
4 (collectively “Takeda”) as follows:

5 **THE PARTIES<sup>1</sup>**

6 1. Handa admits that Plaintiff Takeda Pharmaceutical Company Limited (“TPC”) is  
7 a Japanese corporation with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-  
8 ku, Osaka, Japan. Handa lacks knowledge or information sufficient to form a belief as to the  
9 truth of the remaining allegations in Paragraph 1 of the Corrected First Amended Complaint, and  
10 therefore denies those allegations.

11 2. Handa lacks knowledge or information sufficient to form a belief as to the truth of  
12 the allegations in Paragraph 2 of the Corrected First Amended Complaint, and therefore denies  
13 those allegations.

14 3. Handa admits that Plaintiff Takeda Pharmaceuticals North America, Inc.  
15 (“TPNA”) is a Delaware corporation with its principal place of business at One Takeda Parkway,  
16 Deerfield, IL 60015. Upon information and belief, Handa admits that TPNA is the registered  
17 holder of approved New Drug Application No. 22-287. Handa lacks knowledge or information  
18 sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 of the  
19 Corrected First Amended Complaint, and therefore denies those allegations.

20 4. Handa admits that Plaintiff Takeda Pharmaceuticals LLC (“Takeda LLC”) is a  
21 Delaware limited liability company having a principal place of business at One Takeda Parkway,  
22 Deerfield, IL 60015. Handa lacks knowledge or information sufficient to form a belief as to the  
23 truth of the remaining allegations in Paragraph 4 of the Corrected First Amended Complaint, and  
24 therefore denies those allegations.

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25  
26 <sup>1</sup> For the Court’s convenience, Handa has incorporated the “Headings” that appear  
27 in the Corrected First Amended Complaint. It should be understood, however, that Handa does  
28 not necessarily agree with the characterizations of such Headings, and does not waive any right  
to object to those characterizations.



Handa denies any and all remaining allegations in Paragraph 10 of the Corrected First Amended Complaint.

11. Handa admits that this Court has personal jurisdiction over Handa in this action. Handa admits that Handa is a California corporation and that Handa has a principal place of business within this district. Handa denies any and all remaining allegations in Paragraph 11 of the Corrected First Amended Complaint.

12. For the purposes of this lawsuit only, Handa admits that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Handa denies any and all remaining allegations in Paragraph 12 of the Corrected First Amended Complaint.

### **FACTUAL BACKGROUND**

#### **A. Asserted Patents**

##### **1. The '058 Patent**

13. Handa admits that Exhibit A to the Corrected First Amended Complaint purports to be a copy of United States Patent No. 6,462,058 ("the '058 Patent") titled "Benzimidazole Compound Crystal." Handa admits that the '058 Patent, on its face, (i) states that it was issued on October 8, 2002 to Takeda Chemical Industries, Ltd. as assignee and (ii) names Akira Fujishima, Isao Aoki and Keiji Kamiyama as inventors. Handa lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 13 of the Corrected First Amended Complaint, and therefore denies those allegations.

14. Handa admits that the *Approved Drug Products with Therapeutic Equivalence Evaluations*, published by the FDA (the "Orange Book") lists the expiration date of the '058 Patent as June 15, 2020. Handa denies any and all remaining allegations in Paragraph 14 of the Corrected First Amended Complaint.

##### **2. The '276 Patent**

15. Handa admits that Exhibit B to the Corrected First Amended Complaint purports to be a copy of United States Patent No. 6,664,276 ("the '276 Patent") titled "Benzimidazole Compound Crystal." Handa admits that the '276 Patent, on its face, (i) states that it was issued on December 16, 2003 to Takeda Chemical Industries, Ltd. as assignee and (ii) names Akira

1 Fujishima, Isao Aoki and Keiji Kamiyama as inventors. Handa lacks knowledge or information  
2 sufficient to form a belief as to the truth of the remaining allegations in Paragraph 15 of the  
3 Corrected First Amended Complaint, and therefore denies those allegations.

4 16. Handa admits that the Orange Book lists the expiration date of the '276 Patent as  
5 June 15, 2020. Handa denies any and all remaining allegations in Paragraph 16 of the Corrected  
6 First Amended Complaint.

### 7 **3. The '971 Patent**

8 17. Handa admits that Exhibit C to the Corrected First Amended Complaint purports  
9 to be a copy of United States Patent No. 6,939,971 ("the '971 Patent") titled "Benzimidazole  
10 Compound Crystal." Handa admits that the '971 Patent, on its face, (i) states that it was issued on  
11 September 6, 2005 to Takeda Chemical Industries, Ltd. as assignee and (ii) names Akira  
12 Fujishima, Isao Aoki and Keiji Kamiyama as inventors. Handa lacks knowledge or information  
13 sufficient to form a belief as to the truth of the remaining allegations in Paragraph 17 of the  
14 Corrected First Amended Complaint, and therefore denies those allegations.

15 18. Handa admits that the Orange Book lists the expiration date of the '971 Patent as  
16 June 15, 2020. Handa denies any and all remaining allegations in Paragraph 18 of the Corrected  
17 First Amended Complaint.

### 18 **4. The '282 Patent**

19 19. Handa admits that Exhibit D to the Corrected First Amended Complaint purports  
20 to be a copy of United States Patent No. 7,737,282 ("the '282 Patent") titled "Benzimidazole  
21 Compound Crystal." Handa admits that the '282 Patent, on its face, (i) states that it was issued on  
22 June 15, 2010 to Takeda Chemical Industries, Ltd. as assignee and (ii) names Akira Fujishima,  
23 Isao Aoki and Keiji Kamiyama as inventors. Handa lacks knowledge or information sufficient to  
24 form a belief as to the truth of the remaining allegations in Paragraph 19 of the Corrected First  
25 Amended Complaint, and therefore denies those allegations.

26 20. Handa lacks knowledge or information sufficient to form a belief as to the truth of  
27 the allegations in Paragraph 20 of the Corrected First Amended Complaint, and therefore denies  
28 those allegations.

1                   **5.       The ‘668 Patent**

2           21.     Handa admits that Exhibit E to the Corrected First Amended Complaint purports  
3 to be a copy of United States Patent No. 7,285,668 (“the ‘668 Patent”) titled “Process for the  
4 Crystallization of (R)- or (S)-Lansoprazole.” Handa admits that the ‘668 Patent, on its face,  
5 (i) states that it was issued on October 23, 2007 to Takeda Chemical Industries, Ltd. as assignee  
6 and (ii) names Hideo Hashimoto and Tadashi Urai as inventors. Handa lacks knowledge or  
7 information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 21  
8 of the Corrected First Amended Complaint, and therefore denies those allegations.

9           22.     Handa admits that the Orange Book lists the expiration date of the ‘668 Patent as  
10 June 15, 2020. Handa denies any and all remaining allegations in Paragraph 22 of the Corrected  
11 First Amended Complaint.

12                   **6.       The ‘755 Patent**

13           23.     Handa admits that Exhibit F to the Corrected First Amended Complaint purports  
14 to be a copy of United States Patent No. 7,790,755 (“the ‘755 Patent”) titled “Controlled Release  
15 Preparation.” Handa admits that the ‘755 Patent, on its face, (i) states that it was issued on  
16 September 7, 2010 to Takeda Chemical Industries, Ltd. as assignee and (ii) names Yohko  
17 Akiyama, Takashi Kurasawa, Hiroto Bando, and Naoki Nagahara as inventors. Handa lacks  
18 knowledge or information sufficient to form a belief as to the truth of the remaining allegations  
19 in Paragraph 23 of the Corrected First Amended Complaint, and therefore denies those  
20 allegations.

21           24.     Handa admits that the Orange Book lists the expiration date of the ‘755 Patent as  
22 August 2, 2026. Handa denies any and all remaining allegations in Paragraph 24 of the  
23 Corrected First Amended Complaint.

24                   **B.       DEXILANT**

25           25.     Handa admits that Plaintiff TPNA is the registered holder of approved New Drug  
26 Application No. 22-287. Handa lacks knowledge or information sufficient to form a belief as to  
27 the truth of the remaining allegations in Paragraph 25 of the Corrected First Amended  
28 Complaint, and therefore denies those allegations.

1           26.     Handa lacks knowledge or information sufficient to form a belief as to the truth of  
2 the allegations in Paragraph 26 of the Corrected First Amended Complaint, and therefore denies  
3 those allegations.

4           27.     Handa admits that the '058, '276, '971, '668, and '755 patents are listed in the  
5 Orange Book with respect to the drug DEXILANT (dexlansoprazole) delayed release capsules,  
6 in 30 mg and 60 mg dosage forms. Handa lacks knowledge or information sufficient to form a  
7 belief as to the truth of the remaining allegations in Paragraph 27 of the Corrected First Amended  
8 Complaint, and therefore denies those allegations.

9           **C.     Infringement by Handa**

10          28.     Handa admits that Handa submitted Abbreviated New Drug Application No. 202-  
11 294 ("the ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. § 355(j)). Handa admits that Handa submitted the ANDA in order to obtain approval to  
13 engage in the commercial manufacture, use, importation, offer for sale or sale of a drug product  
14 containing dexlansoprazole, capsules of which contain the equivalent of 30 or 60 mg of  
15 dexlansoprazole (the "Proposed Capsules"). Handa denies any and all remaining allegations in  
16 Paragraph 28 of the Corrected First Amended Complaint.

17          29.     Handa admits that Handa's original ANDA filed on August 24, 2010 sought  
18 approval for a 60 mg dosage form and included a "Paragraph IV" certification under 21 U.S.C.  
19 § 355(j)(2)(A)(vii)(IV) that certified that in the opinion of Handa and to the best of its knowledge  
20 no valid or enforceable claims of the '058 Patent, the '276 Patent, the '971 Patent, and the '668  
21 Patent will be infringed by the manufacture, use, importation, offer for sale or sale of the drug  
22 products for which Handa's ANDA has been submitted. Handa denies any and all other  
23 allegations in Paragraph 29 of the Corrected First Amended Complaint.

24          30.     Handa admits the allegations in Paragraph 30 of the Corrected First Amended  
25 Complaint.

26          31.     Handa admits the allegations in Paragraph 31 of the Corrected First Amended  
27 Complaint.

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1 32. Handa admits the allegations in Paragraph 32 of the Corrected First Amended  
2 Complaint.

3 33. Upon information and belief, Handa admits that on January 14, 2011, TPNA  
4 received a letter (the "Notice Letter") from Handa by Federal Express delivery dated January 13,  
5 2011, notifying TPNA and TPC that the ANDA includes Paragraph IV Certifications with  
6 respect to the '058 Patent, the '276 Patent, the '971 Patent, the '668 Patent, and the '755 Patent.  
7 Handa admits that the letter dated January 13, 2011 was the first Notice Letter Handa sent to  
8 TPNA related to ANDA No. 202-294. Upon information and belief, Handa admits that on  
9 January 18, 2011, TPNA received a second letter from Handa by certified mail dated January 12,  
10 2011. Handa denies any and all remaining allegations in Paragraph 33 of the Corrected First  
11 Amended Complaint.

12 34. Handa denies the allegations in Paragraph 34 of the Corrected First Amended  
13 Complaint.

14 35. Handa denies the allegations in Paragraph 35 of the Corrected First Amended  
15 Complaint.

16 36. Handa admits that Takeda first filed a complaint in this matter on February 23,  
17 2011, a date that is less than 45 days from the date that Takeda received Handa's Notice Letter.  
18 Handa denies any and all remaining allegations in Paragraph 36 of the Corrected First Amended  
19 Complaint.

20 **CLAIMS FOR RELIEF**

21 **COUNT I**

22 **(Patent Infringement of U.S. Patent No. 6,462,058)**

23 37. Handa incorporates by reference and realleges each of the responses to the  
24 allegations in Paragraphs 1 through 36 of the Corrected First Amended Complaint, as set forth in  
25 Paragraphs 1-36 of this Answer, as if fully set forth herein.

26 38. Handa denies the allegations in Paragraph 38 of the Corrected First Amended  
27 Complaint.

28 ///



1 39. Handa denies the allegations in Paragraph 39 of the Corrected First Amended  
2 Complaint.

3 **COUNT II**

4 **(Patent Infringement of U.S. Patent No. 6,664,276)**

5 40. Handa incorporates by reference and realleges each of the responses to the  
6 allegations in Paragraphs 1 through 39 of the Corrected First Amended Complaint, as set forth in  
7 Paragraphs 1-39 of this Answer, as if fully set forth herein.

8 41. Handa denies the allegations in Paragraph 41 of the Corrected First Amended  
9 Complaint.

10 42. Handa denies the allegations in Paragraph 42 of the Corrected First Amended  
11 Complaint.

12 **COUNT III**

13 **(Patent Infringement of U.S. Patent No. 6,939,971)**

14 43. Handa incorporates by reference and realleges each of the responses to the  
15 allegations in Paragraphs 1 through 42 of the Corrected First Amended Complaint, as set forth in  
16 Paragraphs 1-42 of this Answer, as if fully set forth herein.

17 44. Handa denies the allegations in Paragraph 44 of the Corrected First Amended  
18 Complaint.

19 45. Handa denies the allegations in Paragraph 45 of the Corrected First Amended  
20 Complaint.

21 **COUNT IV**

22 **(Patent Infringement of U.S. Patent No. 7,737,282)**

23 46. Handa incorporates by reference and realleges each of the responses to the  
24 allegations in Paragraphs 1 through 45 of the Corrected First Amended Complaint, as set forth in  
25 Paragraphs 1-45 of this Answer, as if fully set forth herein.

26 47. Takeda has not presented this Court with a justiciable controversy over which this  
27 Court has subject-matter jurisdiction. Handa denies the allegations in Paragraph 47 of the  
28 Corrected First Amended Complaint.



1           56.     Handa denies the allegations in Paragraph 56 of the Corrected First Amended  
2 Complaint.

3           57.     Handa denies the allegations in Paragraph 57 of the Corrected First Amended  
4 Complaint.

5           58.     Handa denies the allegations in Paragraph 58 of the Corrected First Amended  
6 Complaint.

7           59.     Handa denies the allegations in Paragraph 59 of the Corrected First Amended  
8 Complaint.

9           60.     Upon information and belief, Handa admits that to the best of its knowledge no  
10 valid or enforceable claims of the '058 Patent, the '276 Patent, the '971 Patent, the '668 Patent,  
11 the '755 Patent, and the '282 Patent will be infringed by the manufacture, importation, use, sale  
12 or offer for sale of the drug products for which Handa's ANDA has been submitted. For claims  
13 relating the '282 Patent, Handa additionally denies that Takeda has presented this Court with a  
14 justiciable controversy over which this Court has subject-matter jurisdiction. Handa denies any  
15 and all remaining allegations in Paragraph 60 of the First Amended Complaint.

16                           **PRAYER FOR RELIEF**

17           Handa denies that Takeda is entitled to the relief requested in Paragraphs A-E of the  
18 Corrected First Amended Complaint.

19                           **AFFIRMATIVE DEFENSES**

20           In further answer to the Corrected First Amended Complaint and as separate, affirmative  
21 defenses thereto, Handa alleges as follows:

22                           **First Affirmative Defense:**

23           61.     Handa does not infringe any valid or enforceable claim of the '058 Patent.

24                           **Second Affirmative Defense**

25           62.     The claims of the '058 Patent are invalid for failure to meet the provisions of one  
26 or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

27                           **Third Affirmative Defense**

28           63.     Handa does not infringe any valid or enforceable claim of the '276 Patent.

**Fourth Affirmative Defense**

64. The claims of the '276 Patent are invalid for failure to meet the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**Fifth Affirmative Defense**

65. Handa does not infringe any valid or enforceable claim of the '971 Patent.

**Sixth Affirmative Defense**

66. The claims of the '971 Patent are invalid for failure to meet the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**Seventh Affirmative Defense**

67. Handa does not infringe any valid or enforceable claim of the '668 Patent.

**Eighth Affirmative Defense**

68. The claims of the '668 Patent are invalid for failure to meet the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**Ninth Affirmative Defense**

69. Handa does not infringe any valid or enforceable claim of the '755 Patent.

**Tenth Affirmative Defense**

70. The claims of the '755 Patent are invalid for failure to meet the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**Eleventh Affirmative Defense**

71. The Corrected First Amended Complaint fails to state a claim upon which relief can be granted for alleged infringement of the '282 Patent under 35 U.S.C. § 271(e)(2).

**Twelfth Affirmative Defense**

72. This Court lacks jurisdiction over the subject matter relating to the '282 Patent because Takeda has not established a justiciable case or controversy required for this Court's jurisdiction.

**Thirteenth Affirmative Defense**

73. To the extent that this Court exercises jurisdiction over the subject matter relating to the '282 Patent, Handa does not infringe any valid or enforceable claim of the '282 Patent.

**Fourteenth Affirmative Defense**

74. To the extent that this Court exercises jurisdiction over the subject matter relating to the '282 Patent, the claims of the '282 Patent are invalid for failure to meet the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**COUNTERCLAIMS**

Defendant/Counterclaimant, Handa Pharmaceuticals, LLC ("Handa") brings the following Counterclaims against Plaintiffs/Counterdefendants Takeda Pharmaceutical Co., Ltd., Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") for a declaratory judgment of patent non-infringement and invalidity.

**PARTIES**

75. Counterclaimant Handa is a limited liability company organized under the laws of California, having its principal place of business at 39465 Paseo Padre Parkway, Suite 2600, Fremont, CA 94538.

76. On information and belief, and based on Takeda's allegations, Counterdefendant Takeda Pharmaceutical Company Limited ("TPC") is a Japanese Corporation with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan.

77. On information and belief, and based on Takeda's allegations, Counterdefendant Takeda Pharmaceuticals North America, Inc. ("TPNA") is a Delaware corporation with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

78. On information and belief, and based on Takeda's allegations, Counterdefendant Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

79. On information and belief, and based on Takeda's allegations, Counterdefendant Takeda Pharmaceuticals America, Inc. ("TPA") is a Delaware corporation, with its principal place of business at One Takeda Parkway, Deerfield, IL 60015.

80. On information and belief, and based on Takeda's allegations, TPC is the owner of record and assignee of U.S. Patent No. 6,462,058 ("the '058 Patent"), U.S. Patent No.

6,664,276 (“the ‘276 Patent”), U.S. Patent No. 6,939,971 (“the ‘971 Patent”), U.S. Patent No. 7,285,668 (“the ‘668 Patent”), U.S. Patent No. 7,790,755 (“the ‘755 Patent”), and U.S. Patent No. 7,7373,282 (“the ‘282 Patent”).

#### **JURISDICTION AND VENUE**

81. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

82. This is an action based upon an actual controversy, arising under 35 U.S.C. § 271(e)(2), between the parties concerning the invalidity and/or non-infringement of the ‘058 Patent, the ‘276 Patent, the ‘971 Patent, the ‘668 Patent, and the ‘755 Patent and Handa’s right to continue to seek approval of ANDA No. 202-294 for a dextansoprazole product.

83. To the extent that this Court exercises subject-matter jurisdiction over claims relating to the ‘282 patent, Handa alternatively and additionally alleges counterclaims, pursuant to 28 U.S.C. §§ 2201 and 2202, that Handa does not infringe any claims of that patent and that the claims of that patent are invalid.<sup>2</sup>

84. This Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202 and/or 35 U.S.C. § 271(e)(2).

85. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Takeda’s choice of forum.

86. Handa has submitted, and is continuing to seek FDA approval of, ANDA No. 202-294 directed to a product containing dextansoprazole. Handa’s ANDA seeks approval for Handa to engage in the commercial manufacture, importation, use, or sale of dextansoprazole products, which Takeda alleges infringes the ‘058 Patent, the ‘276 Patent, the ‘971 Patent, the ‘668 Patent, the ‘755 Patent, and the ‘282 Patent.

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<sup>2</sup> Handa asserts Counterclaims relating to the 282 Patent claim only insofar as, and to the extent that, the Court exercises jurisdiction over claims relating to the ‘282 Patent. By asserting these Counterclaims, Handa is not admitting that Takeda has provided a basis for this Court’s subject-matter jurisdiction over the ‘282 Patent. Handa does not waive, and reserves all, rights to challenge Takeda’s assertion of subject-matter jurisdiction as to the ‘282 Patent.

1           87.     Counterdefendant Takeda has filed in this Court an infringement action to enforce  
2 the '058 Patent, the '276 Patent, the '971 Patent, the '668 Patent, the '755 Patent, and the '282  
3 Patent against Handa. Handa has denied that it has, continues, or will infringe any valid and  
4 enforceable claim of the '058 Patent, the '276 Patent, the '971 Patent, the '668 Patent, the '755  
5 Patent and/or the '282 Patent. Handa has further asserted that to the extent Takada establishes  
6 that Handa infringes any claim in the '058 Patent, the '276 Patent, the '971 Patent, the '668  
7 Patent, the '755 Patent, and the '282 Patent, those claims are invalid for failure to satisfy one or  
8 more of the provisions of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102,  
9 103, and/or 112.

10           88.     In view of the foregoing, a conflict of asserted rights has arisen between Handa  
11 and Takeda with respect to the non-infringement and invalidity of the relevant claims of the '058  
12 Patent, the '276 Patent, the '971 Patent, the '668 Patent, and/or the '755 Patent and as to Handa's  
13 right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer  
14 for sale, or sale of its dextansoprazole products. An actual controversy therefore exists between  
15 Takeda and Handa with respect to these patents.

16           89.     To the extent that this Court exercises subject-matter jurisdiction over the parties  
17 relating to the invalidity and/or non-infringement of the '282 patent, Handa alternatively and  
18 additionally alleges that an actual controversy exists with respect to the non-infringement and  
19 invalidity of the relevant claims of the '282 Patent and as to Handa's right to engage in the  
20 commercial manufacture, importation, use, offer for sale, or sale of its dextansoprazole products.

21           **FIRST COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF**  
22                                   **THE '058 PATENT**

23           90.     Handa incorporates by reference and realleges Paragraphs 75-89 as if set forth  
24 specifically herein.

25           91.     Handa does not infringe any valid and enforceable claim of the '058 Patent.

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27     ///

28     ///

**SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘058 PATENT**

92. Handa incorporates by reference and realleges Paragraphs 75-91 as if set forth specifically herein.

93. The ‘058 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**THIRD COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF  
THE ‘276 PATENT**

94. Handa incorporates by reference and realleges Paragraphs 75-93 as if set forth specifically herein.

95. Handa does not infringe any valid and enforceable claim of the ‘276 Patent.

**FOURTH COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘276 PATENT**

96. Handa incorporates by reference and realleges Paragraphs 75-95 as if set forth specifically herein.

97. The ‘276 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**FIFTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF  
THE ‘971 PATENT**

98. Handa incorporates by reference and realleges Paragraphs 75-97 as if set forth specifically herein.

99. Handa does not infringe any valid and enforceable claim of the ‘971 Patent.

**SIXTH COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘971 PATENT**

100. Handa incorporates by reference and realleges Paragraphs 75-99 as if set forth specifically herein.

101. The ‘971 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.



**SEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF  
THE ‘668 PATENT**

102. Handa incorporates by reference and realleges Paragraphs 75-101 as if set forth specifically herein.

103. Handa does not infringe any valid and enforceable claim of the ‘668 Patent.

**EIGHTH COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘668 PATENT**

104. Handa incorporates by reference and realleges Paragraphs 75-103 as if set forth specifically herein.

105. The ‘668 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**NINTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF  
THE ‘755 PATENT**

106. Handa incorporates by reference and realleges Paragraphs 75-105 as if set forth specifically herein.

107. Handa does not infringe any valid and enforceable claim of the ‘755 Patent.

**TENTH COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘755 PATENT**

108. Handa incorporates by reference and realleges Paragraphs 75-107 as if set forth specifically herein.

109. The ‘755 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**ELEVENTH COUNTERCLAIM – DECLARATION OF NONINFRINGEMENT OF  
THE ‘282 PATENT**

110. Handa incorporates by reference and realleges Paragraphs 75-109 as if set forth specifically herein.

111. To the extent that this Court exercises subject-matter jurisdiction relating to the ‘282 patent, Handa does not infringe any valid and enforceable claim of the ‘282 Patent.

**TWELFTH COUNTERCLAIM – DECLARATION OF INVALIDITY OF  
THE ‘282 PATENT**

112. Handa incorporates by reference and realleges Paragraphs 75-111 as if set forth specifically herein.

113. To the extent that this Court exercises subject-matter jurisdiction relating to the ‘282 patent, the ‘282 Patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103 and/or 112 of Title 35 of the United States Code.

**DEMAND FOR JUDGMENT**

WHEREFORE, Handa prays for the following relief:

A. That all claims against Handa be dismissed with prejudice and that all relief requested by Takeda be denied;

B. That a judgment be entered declaring that Handa has not, and does not, infringe any valid claim of United States Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,285,668, and 7,790,755, that Handa has a lawful right to obtain FDA approval of ANDA No. 202-294 for its 30 mg and 60 mg dexlansoprazole products, and further that Handa has a lawful right to manufacture, import, use, sell and/or offer to sell its 30 mg and 60 mg strength dexlansoprazole ANDA products once approved by the FDA;

C. That a judgment be entered declaring that the claims of United States Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,285,668, and 7,790,755 are invalid;

D. To the extent that this Court exercises subject matter jurisdiction related to the ‘282 Patent, that a judgment be entered declaring that Handa has not, and does not, infringe any valid claim of United States Patent No. 7,737,282, that Handa has a lawful right to manufacture, import, use, sell and/or offer to sell its 30 mg and 60 mg strength dexlansoprazole ANDA products once approved by the FDA;

E. That a judgment be entered declaring that the claims of United States Patent No. 7,737,282 are invalid;

F. That Plaintiffs/Counterdefendants and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be

1 preliminarily and permanently enjoined from threatening or initiating infringement litigation  
2 against Handa or any of its customers, dealers or suppliers, or any prospective or present sellers,  
3 dealers, distributors or customers of Handa, or charging any of them either orally or in writing  
4 with infringement of United States Patent Nos. 6,462,058, 6,664,276, 6,939,971, 7,285,668, and  
5 7,790,755;

6 G. That Plaintiffs/Counterdefendants and their agents, representatives, attorneys and  
7 those persons in active concert or participation with them who receive actual notice thereof, be  
8 preliminarily and permanently enjoined from threatening or initiating infringement litigation  
9 against Handa or any of its customers, dealers or suppliers, or any prospective or present sellers,  
10 dealers, distributors or customers of Handa, or charging any of them either orally or in writing  
11 with infringement of United States Patent No. 7,737,282;

12 H. That a judgment be entered, declaring that this action is an exceptional case  
13 within the meaning of 35 U.S.C. § 285 and that Handa is entitled to recover its reasonable  
14 attorneys' fees upon prevailing in this action;

15 I. That Handa be awarded costs, attorneys' fees and other relief, both legal and  
16 equitable, to which they may be justly entitled; and

17 J. That Handa be awarded such other and further relief as is just and proper.

18 Respectfully submitted,

19 KNOBBE, MARTENS, OLSON & BEAR, LLP  
20

21 Dated: April 29, 2011

22 By: /s/ William R. Zimmerman

23 William R. Zimmerman

24 Steven A. Maddox

25 Frances L. Pai

26 Attorneys for Defendant/Counterclaimant  
27 Handa Pharmaceuticals, LLC  
28

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